UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
	)	Investigation No. 337-TA-293
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	

ORDER

On February 1, 1989, Bristol-Myers Company (since renamed Bristol-Myers Squibb Company) ("Bristol") filed a complaint with the Commission alleging violations of section 337 in the importation and sale of certain crystalline cefadroxil monohydrate. The complaint alleged infringement of claim 1 of U.S. Letters Patent 4,504,657 ("the '657 patent") owned by Bristol.

The Commission instituted an investigation into the allegations of Bristol's complaint and published a notice of investigation in the Federal Register. 54 F.R. 10740 (March 15, 1989). The notice named the following respondents: (1) Biocraft Laboratories, Inc. of Elmwood Park, N.J.; (2) Gema, S.A. of Barcelona, Spain; (3) Kalipharma, Inc. of Elizabeth, N.J.; (4) Purepac Pharmaceutical Co. of Elizabeth, N.J.; (5) Istituto Biochimico Italiano Industria Giovanni Lorenzini S A. of Milan, Italy; and (6) Institut Biochimique, S.A. of Massagno, Switzerland.

On December 15, 1989, the presiding administrative law judge (ALJ) issued an initial determination (ID) finding no violation of section 337 in this investigation. On January 25, 1990, the Commission issued a notice of a decision to review the ID's findings and conclusions that the '657 patent is invalid for obviousness under 35 U.S.C. § 103. The Commission determined not to review the remainder of the ID, except for two sentences that it determined to strike. 55 F.R. 3282 (Jan. 31,

1990). The ALJ's findings on those issues in the ID that the Commission determined not to review or strike became the determinations of the Commission.

The Commission did not request further briefing on the issues under review, but did request written submissions from interested persons on the issues of remedy, the public interest, and bonding. The Commission received such submissions from all parties except Gema S.A. It also received submissions from Zenith Laboratories, Inc. and the Department of Medical Assistance of the State of Georgia.

Having examined the record in this investigation, including the ID, and the arguments submitted by the parties in their petitions for review and replies thereto, the Commission has determined to reverse that portion of the ID concluding that the '657 patent is invalid for obviousness under 35 U.S.C. § 103. Because those portions of the ID that the Commission determined not to review (1) found that Bristol had established all elements of a section 337 violation except for patent valid and (2) rejected respondents' remaining arguments that the '657 patent is invalid or unenforceable, the Commission concludes that there is a violation of section 337 in the importation, sale for importation, or sale in the United States of crystalline cefadroxil monohydrate.

Having determined that there is a violation of section 337, the Commission considered the questions of the appropriate remedy, bonding during the Presidential review period, and whether the statutory public whether the statutory public interest considerations preclude the issuance of a remedy. The Commission considered the submissions of the parties, comments received from other interested persons, and the entire record in this investigation. The Commission has determined that a limited exclusion order and cease and desist orders directed to all U.S. respondents are the appropriate form of relief. The Commission has further determined that the public interest factors enumerated in 19

U.S.C. § 1337(d) and (f) do not preclude the issuance of the aforementioned relief. The Commission has established that respondents' bond under the exclusion order and the cease and desist orders during the Presidential review period shall be in the amount of sixty-eight (68) percent of the entered value of the imported articles.

Accordingly, it is hereby ORDERED THAT --

1. Crystalline cefadroxil monohydrate capsules and crystalline cefadroxil monohydrate bulk powder manufactured abroad by Gema, S.A. of Spain; Istituto Biochimico Italiano Industria Giovanni Lorenzini S.p.A. of Italy; and Institut Biochimique, S.A. of Switzerland; or any of their affiliated companies, parents, subsidiaries, licensees, contractors, or other related entities, or their successors or assigns, that is covered by claim 1 of U.S. Letters Patent 4,504,657, are excluded from entry into the United States for the remaining term of the patent, except under license of the patent owner.

2. In accordance with 19 U.S.C. § 1337(l), the provisions of this order do not apply to crystalline cefadroxil monohydrate capsules or bulk powder imported by or for the United States.

3. The articles identified in paragraph (1) of this **Order** are entitle to entry into the United States under bond in the amount of sixty eight (68) percent of their entered value from the day after this **Order** is received by the President, pursuant to 19 U.S.C. § 1337(j)(3), until such time as the President notifies the Commission that he approves or disapproves this **Order,** but, in a event, no later than 60 days after the date of receipt of this **Order** by the President.

4. The attached cease and desist orders are issued **to Biocraft** Laboratories, Inc., Kalipharma, Inc., and Purepac Pharmaceutical Co.

5. The Commission may amend this **Order** in accordance with the procedure described in section 211.57 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.57.

6. A copy of this **Order** shall be served upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, and the Federal Trade Commission.

7. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

Kenneth R. Mason
Secretary

Issued: March 15, 1990